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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,684	01/28/2004	Nabil L. Muhanna	126013-1003	2069
7590 03/09/2010 STEVEN E. ROSS, IP SECTION KENNETH T. EMANUELSON GARDERE WYNNE SEWELL LLP 1601 ELM STREET, SUITE 3000 DALLAS, TX 75201				
EXAMINER SNOW, BRUCE EDWARD				
ART UNIT 3738		PAPER NUMBER		
MAIL DATE 03/09/2010		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/766,684

Applicant(s)

MUHANNA ET AL.

Examiner

Bruce E. Snow

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/14/09.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 and 21-42 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 21-32, 34-36, 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

comprises complementary articulating surfaces of two components. It is the Examiner strong opinion that the articulating surface of the complementary component (see figure 1b) would be convex along the mid-sagittal plane such that they would be "complementary". **Shelokov teaches that this complementary plane P1 is convex. See 5:66-6:3 and figure 1b.**

Regarding the Linscheid et al rejection, again, it is the Examiner's position that the device of is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.* Additionally, the prosthetic is fully capable of being implanted into an intervertebral disc of some type of animal.

Applicant's arguments directed to Linscheid et al teaching two components is not commensurate with the scope of the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 21-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 claims a "*superior surface that is substantially comprised of a single articulating surface*". The Examiner notes that applicant failed to indicate support in the original disclosure for this new limitation. It is the Examiner's position that either component (the elected embodiment shown below) has only a single articulating surface. To claim "substantially a single articulating surface" is broader and new matter.

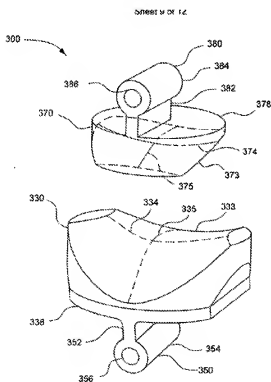


FIG. 9

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 21-32, 34-36, 42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 19-36 of copending Application No. 11/648,384. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because are a broader language for the same device:

A prosthetic disc comprising:

a disc body, having a first surface that is a concave-convex articulating surface and a second surface as a base adapted for fixation to a first bone surface.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

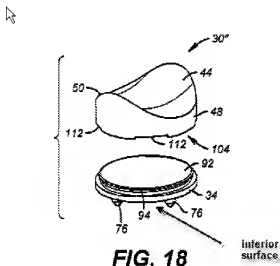
Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burkinshaw (6,602,292).

Burkinshaw teaches a prosthetic disc comprising:

First interpretation: a disc body 30 having a first surface 44 that is a concave-convex articulating surface and a second surface 46 as a base **adapted** for fixation to a first bone surface, wherein the concave-convex articulating surface is hyperbolic paraboloid (see 4:8) meeting all claim limitations.

Regarding the base surface 46, note that the non-flat surface configuration including elements such as 52 and 54 shown in figure 10, would act as an anchor point for bone cement fixation. Therefore, the articulating surface and second surface are relatively fixed.

Second interpretation: a disc body 30 having a superior surface 44 that is a concave-convex articulating surface meeting all claimed limitations and a second inferior surface adapted for fixation to a vertebral bone surface, wherein the concave-convex articulating surface is hyperbolic paraboloid (see 4:8).



It is the Examiner's position that the two components (32, 34) of Burkinshaw are rotatably coupled but snap together preventing separation which is interpreted as being "fixed" together. Therefore, the articulating surface is fixed relative to the inferior surface. The Examiner notes that Burkinshaw teaches the advantages of having said two components rotatably/translationally coupled over the art. It is within the scope of the teachings that the components could be non-rotatably and non-translationally coupled (inherent) or at a minimum, obvious to try with predictable (rejection under 35 U.S.C. 103(a)).

It is the Examiner's position that the device of Burkinshaw is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a*

"recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

Claim 24, it is possibly that the disc body was made of separate components connected together. This claim has been interpreted as a product by process limitation which fails to differentiate. The second interpretation uses a two component configuration.

Claims 26-28, see 5:48 et seq.

Claim 29 is functional language only.

Claim 30, fully capable of.

Claim 34 is not positively claiming the second body.

Regarding claim 42, "has a hyperbolic paraboloid shape" is interpreted as being broader and does not limit explicitly to being a hyperbolic paraboloid.

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelokov (6,039,763).

Shelokov teaches a prosthetic disc comprising:
a first and second disc bodies 1, 10 having complimentary saddle shaped articulating surfaces each surface being one of concave and convex in a first plane and the other of concave and convex in a perpendicular plane to the first. Shelokov teaches, *"the articulating surfaces (3,12) can be regularly or irregularly shaped as at least partially complementary portions of.. paraboloids (6:51 et seq.)."*

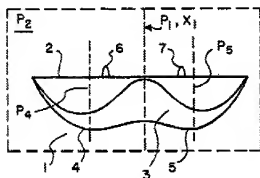
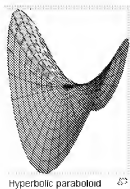
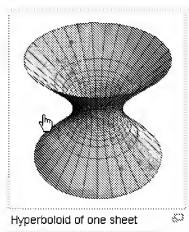


FIG. 1b

Wikipedia teaches, *"In mathematics, a **paraboloid** is a quadric surface of special kind. There are two kinds of paraboloids: **elliptic** and **hyperbolic**."*



Referring to the first and second disc bodies of Shelokov, the articulating surface 3, 12 (between lines P4 and P5) are a clearly a hyperbolic paraboloid shape and not an elliptic paraboloid. As quoted above, the surfaces can be regular shape paraboloids which are hyperbolic as taught from the drawings. Hyperbolic paraboloids are inherently concave-convex. Shelokov teaches that the plane P1 is convex; see 5:66-6:3. Additionally, Shelokov teaches the articulating surfaces can be a hyperboloid which meets all claims. Same for claim 35.



Regarding claim 19, a midsagittal plane is solely convex.

Note that the second surface 2 of body 1 is fixed relative to the articulating surface 3.

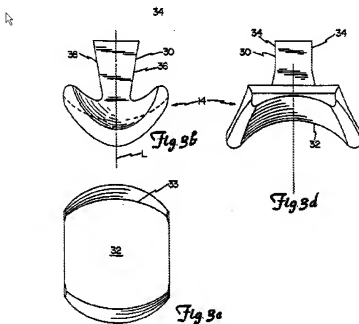
Regarding claim 42, "the superior articulating surface has a single shape characterized as a hyperbolic paraboloid", the single shape of portions 3, 12 is a hyperbolic paraboloid.

Regarding claims 24-27, see at least 9:47 et seq. teaching at least coatings.

Claims 19, 21-32, 34-36, 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Linscheid et al (5,405,400).

Linscheid et al teaches:

A joint prosthetic comprising a disc body 14 having a first articulating surface 32 which is a hyperbolic paraboloid shape (see 3:56) and second surface which is relatively fixed. Clearly the midsagittal plane is solely convex as shown in figure 3b.



It is the Examiner's position that the device of is sized and configured and fully capable of being used in the disc. MPEP 2114 teaches: *A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.* Additionally, the prosthetic is fully capable of being implanted into a intervertebral disc of some type of animal.

All other limitations are self-evident.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruce E Snow/

Primary Examiner, Art Unit 3738